K092201 #1/2

AUG 20 2009

ADVANCE® 913 Medial Pivot
SPECIAL 510(k) Summary of Safety and Effectiveness

In accordance with the food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the ADVANCE® 913 Medial Pivot Tibial Insert and Base.

Submitted By:	Wright Medical Technology, Inc.
Primary Contact:	Sarah Fairfield
Proprietary Name:	ADVANCE® 913 Medial Pivot Tibial Base ADVANCE® 913 Medial Pivot Tibial Insert
Common Name:	Tibial Base Tibial Insert
Classification Name and Reference:	21 CFR 888.3560 Knee, Patellofemorotibial, Semi-constrained, cemented, Polymer/ metal/polymer
Device Product Code and Panel Code:	Orthopedics/87/ JWH

A. INTENDED USES/ INDICATIONS

The ADVANCE® 913 Medial Pivot Tibial Insert and ADVANCE® 913 Medial Pivot Tibial Base are indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2) inflammatory degenerative joint disease including rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and
5) treatment of fractures that are unmanageable using other techniques.

ADVANCE® 913 Medial Pivot Tibial Base and Insert Components are for use with bone cement.

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B. DEVICE DESCRIPTION

Tibial Insert

The design features of the ADVANCE® 913 Medial Pivot Tibial Insert are summarized below:

- Manufactured from UHMWPE conforming to ASTM F648
- Sizes: 1-5 Left & Right
- Thickness: 10, 12, 14, 17 mm

Tibial Base

The design features of the ADVANCE® 913 Medial Pivot Tibial Base are summarized below:

- Manufactured from Cobalt Chrome alloy conforming to ASTM F75
- Sizes: 1-5 plus
- Symmetrical
- No screw holes

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The indications for use for the ADVANCE® 913 Medial Pivot Tibial Insert and the ADVANCE® 913 Medial Pivot Tibial Base are identical to the indications for use for the previously cleared predicate devices. The design features of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified device has not changed relative to the predicate devices. The safety and effectiveness of the ADVANCE® 913 Medial Pivot Tibial Insert and the ADVANCE® 913 Medial Pivot Tibial Base is adequately supported by the substantial equivalence information, materials information and the analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
% Ms. Sarah Fairfield
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

AUG 20 2009

Re: K092201
Trade/Device Name: ADVANCE 913 Medial Pivot Tibial Insert, ADVANCE 913 Medial Pivot Tibial Base
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: July 14, 2009
Received: July 22, 2009

Dear Ms. Fairfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers. International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092201

Device Name: ADVANCE® 913 Medial Pivot Tibial Insert
ADVANCE® 913 Medial Pivot Tibial Base

Indications For Use:

The ADVANCE® 913 Medial Pivot Tibial Insert and the ADVANCE® 913 Medial Pivot Tibial Base are indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

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5) treatment of fractures that are unmanageable using other techniques.

ADVANCE® 913 Medial Pivot Tibial Base and Insert Components are for use with bone cement.

Prescription Use xxx AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092201